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RAMDHANIE, BOBBY	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/567,002	Applicant(s) HANDIQUE ET AL.	
	Examiner Bobby Ramdhanie, Ph.D.	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 January 2006*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *31 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

2. Claims 1, 2, 5-10, 14, 15, & 17-21 are rejected under 35 U.S.C. 102(e) as being anticipated by Parunak et al (WO03/012406). Regarding Claim 1, Parunak et al teaches a microfluidic, device, including: A). An input port for receiving a particle-containing

liquidic sample (Page 12 Line 17); B). A retention member in communication with the input port and configured to spatially separate particles of the particle-containing liquidic sample from a first portion of the liquid of the particle containing fluidic sample (Page 3, lines 17-27); and C). A pressure actuator configured to recombine at least some of the separated particles with a subset of the first portion of the liquid separated from the particles (Page 3 line 28 - Page 4 line 5).

3. For Claim 2, Parunak et al teaches the microfluidic device of Claim 1, wherein the pressure actuator is configured to reduce a gas pressure inside the device and in communication with the particles (Page 15 lines 10-25).

4. For Claim 5, Parunak et al teaches the microfluidic device of claim 1, wherein the retention member is a filter (Page 3 lines 25-27).

5. For Claim 6, Parunak et al teaches the microfluidic device of claim 1, wherein the device includes a reservoir (Page 12, Enrichment Module) configured to receive at least some of the first portion of the liquid, and wherein a pressure within the reservoir increases upon receiving the first portion of liquid (Page 12, lines 18-20). Examiner takes the position that as the particles continue to increase in this region, pressure build up is an inherent property of this region.

6. For Claim 7, Parunak et al teaches a method for processing a particle-containing liquidic sample, including: A). Inputting a particle-containing liquidic sample into a microliquidic device including a retention member including a first surface (Page 12, 16-20); spatially separating a first portion of the liquid of the liquidic sample from particles of the liquidic sample by passing the first portion of the liquid through at least the first

surface of the retention member (Page 3 lines 17-20); and recombining the retained particles with a subset of the first portion of the liquid (Page 3 line 28-Page 4 line 14).

7. For Claim 8, Parunak et al teaches the method of claim 7, wherein recombining the retained particles includes reducing a pressure within the microfluidic device (Page 15 lines 16-25).

8. For Claim 9, Parunak et al teaches a microfluidic device for processing a particle-containing liquid sample, including: A). An enrichment region (Page 3 line 19), including: B). A retention member configured so that liquid of a particle-containing liquid sample received therein exits the enrichment region along an exit path including a first surface of the retention member and particles of the particle-containing liquid sample are retained by the retention member (Page 3 lines 17-27); and C). A pressure actuator configured to introduce fluid into the enrichment region along an entry path including the first surface of the retention member (Page 3 lines 28 - Page 4 line 5).

9. For Claim 10, Parunak et al teaches a method for enriching a sample, including: introducing a particle-containing fluidic sample to a microfluidic network; A). Applying a pressure to the fluidic sample to expel a fast amount of the fluid of the fluidic sample through a filter configured to retain particles of the fluidic sample within the microfluidic network (Page 3 lines 17-27) and B). Subjecting retained particles of the fluidic sample to a reduced pressure to cause a second, smaller amount of fluid to enter the microfluidic network through the filter and entrain the particles to form an enriched particle-containing sample (Page 15 lines 16-25).

10. For Claim 14, Parunak et al teaches a device for concentrating particles of a particle-containing fluid, including: A). A substantially planar substrate including a microfluidic network; and B). A mechanically actuated vacuum generator integral with the substrate, the vacuum generator including an expandable chamber in fluidic communication with the microfluidic network (Page 15 lines 14-15).

11. For Claim 15, Parunak et al teaches a device for concentrating particles of a particle containing fluid, including: A). A first substrate (Page 9 line 3) and B). A second substrate (Page 9 line 3), the first and second substrates defining there between: C). At least a portion of a microfluidic network (Page 9 lines 3-4), the microfluidic network including a first end and a second end, the first end configured to receive a sample including a particle-containing fluid (Page 14 line 9) ; a chamber (Page 14 line 10), the second end of the microfluidic network being in fluidic communication with the chamber (Page 14 Line 12); a manually actuated member operatively associated with the chamber and configured, upon actuation, to increase a volume thereof, whereupon, a pressure within the chamber decreases drawing fluid toward the second end of the microfluidic network(Page 15 lines 16-25).

12. For Claim 17, Parunak et al teaches a microfluidic device, comprising: A). A first planar substrate comprising first and second sides(Figure 2 Item 138); B). A second substrate mated to the first side of the first planar substrate (Figure 2 Item 130); C). A third substrate mated to the second side of the first planar substrate (Figure 2 Item 140); wherein, the first side of the first planar substrate and the second substrate define therebetween: D). A channel configured to accommodate microfluidic samples (Figure 2

Item 134); and an amount of thermally responsive substance (TRS) disposed adjacent the channel, the TRS having a stationary state at a first temperature and a movable state at a second, higher temperature (Page 12 lines 25-28). The second side of the first planar substrate and the second substrate define therebetween a chamber in gaseous communication with the TRS (Page 12 line 25-28).

13. For Claim 18, Parunak et al teaches a microfluidic device, comprising: A). A lysing chamber having a volume of less than 10 microliters (Page 9 lines 17-18); B). An upstream channel leading to the lysing chamber and a downstream channel extending from the lysing chamber (Figure 3 Item 166); C). A mass of a temperature responsive substance (TRS) disposed in the downstream channel, the mass of TRS configured (a) to inhibit downstream passage of material when material is introduced to the lysing chamber and (b) to pass downstream upon being heated to allow downstream passage of material from the lysing chamber (Page 12 lines 25-28).

14. For Claim 19, Parunak et al teaches a method for lysing cells of a cell-containing sample, comprising: A) Introducing the cell-containing sample to a lysing chamber of a microfluidic device (Figure 3 Item 166), a downstream channel extending downstream from the lysing chamber, the lysing chamber having a volume of less than 10 microliters (Page 9 lines 17-18), a mass of a temperature responsive substance (TRS) disposed in the downstream from the lysing chamber inhibiting downstream passage of the sample from the lysing chamber (Page 12 lines 25-28); heating cells within the lysing chamber to a temperature sufficient to release intracellular material (Page 4 lines 10-14); and

heating the TRS, whereupon the TRS and intracellular material pass downstream (Page 12 lines 25-28).

15. For Claim 20, Parunak et al teaches a method for processing a sample, comprising: A). Introducing a sample to a microfluidic network of a microfluidic device, wherein the introduction generates a gas pressure within a reservoir in communication with the microfluidic network (Page 3 lines 28-30); B). Storing the pressure within the reservoir; and then using the gas pressure to move the sample within the microfluidic network (Page 3 line 30 to Page 4 line 1).

16. For Claim 21, Parunak et al teaches the method of claim 20, wherein using the gas pressure comprises heating a temperature responsive substance within the microfluidic device (Page 4 lines 1-5).

Claim Rejections - 35 USC § 103

17. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

18. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

19. Claims 3, 4, 11, 12, 13, & 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parunak et al. Regarding Claim 3, Parunak et al teaches the microfluidic device of Claim 1. Parunak et al does not teach a ratio of a volume of the subset of the first portion of liquid to the first portion of fluid is at least 1%. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Parunak et al to develop a ratio of a volume of the subset of the first portion of liquid to the first portion of fluid to be at least 1% because it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F2d. 272, 205 USPQ 215 (CCPA 1980).

20. For Claim 4, Parunak et al teaches the microfluidic device of Claim 1. Parunak et al does not teach a ratio of a volume of the subset of the first portion of liquid to the first

portion of fluid is at least 25%. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Parunak et al to develop a ratio of a volume of the subset of the first portion of liquid to the first portion of fluid to be at least 1% because it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F2d. 272, 205 USPQ 215 (CCPA 1980).

21. For Claim 11, Parunak et al teaches all of the claim limitations according to Claim 10. Parunak does not teach that applying pressure includes mating a syringe to an input port of the microfluidic network. It would have been obvious to one of ordinary skill in the art to modify Parunak et al, to apply pressure mating a syringe to an input port of the microfluidic network because according to Parunak et al, the enrichment zone 931 can be configured to receive samples directly, such as by injection. Examiner takes the position that one of ordinary skill in the art would know that injection may be carried out via a syringe.

22. For Claim 12, Parunak et al teaches all of the claim limitations according to Claim 11. Parunak et al further teaches the step of introducing the particle-containing fluidic sample also applies the pressure to expel the first amount of fluid (Page 3 lines 17-27).

23. For Claim 13, Parunak et al teaches all of the claim limitations according to Claim 12. Parunak et al further teaches the method of claim 12, wherein subjecting the particles of the fluidic sample to a reduced pressure includes creating a vacuum within the rnicrofluidic network and placing the vacuum in communication with the retained particles (Page 15 lines 16-25).

24. For Claim 16, Parunak et al teaches a method for enriching a particle-containing fluidic sample, including: A). Contacting a particle-containing fluidic sample with a filter so that a first portion of the fluid of the PCFS passes through the filter and particles of the PCFS are retained by the filter (Page 3 lines 17-26), the fluid passing through the filter entering a chamber and increasing a pressure therein (Page 3 lines 17-26). Parunak et al does not teach allowing a second, smaller portion of the fluid to pass back through the filter and recombine with the particles retained by the filter. It would have been obvious to one or ordinary skill in the art at the time the invention was made to modify Parunak et al to include a step that would allow a second smaller portion, or a third or a fourth or fifth portion of the fluid to pass back through the filter and recombine with the particles retained by the filter because it is common for bacterial lysate to clog filters and retain compounds in the debris that is left behind.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bobby Ramdhanie, Ph.D. whose telephone number is 570-270-3240. The examiner can normally be reached on Mon-Fri 8-5 (Alt Fri off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Walter Griffin can be reached on 571-272-1447. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BR

Walter D. Griffin

WALTER D. GRIFFIN
SUPERVISORY PATENT EXAMINER